In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 18-0411V UNPUBLISHED

AMBER ETHERIDGE,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: October 30, 2020

Special Processing Unit (SPU); Dismissal; Untimely Filed; Onset; Table Injury; Lookback Provision; Influenza (Flu) Vaccine; Guillain-Barré Syndrome (GBS)

Milton Clay Ragsdale, IV, Ragsdale LLC, Birmingham, AL, for petitioner.

Darryl R. Wishard, U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

On March 19, 2018, Amber Etheridge filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). "Petitioner alleges that she incurred Guillain-Barré syndrome due to the influenza ("flu") vaccine she received on September 24, 2012, casting her claim as a Table injury under 42 U.S.C. §300aa-14, as amended effective March 21, 2017." Petition at ¶ 7. The case was assigned to the Special Processing Unit of the Office of Special Masters.

On March 15, 2019, Respondent filed his Rule 4(c) Report, arguing that Petitioner has failed to establish that her petition was timely filed, or that she suffered the residual effects of her injury for more than six months. ECF No. 23; see Section 16 (requirements

¹ Because this unpublished Decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

for a timely filed petition); Section 16(c)(1)(D)(i) (statutory six-month requirement). Accompanying the Rule 4(c) Report was a motion seeking the claim's dismissal. ECF No. 24. Now, having considered both the motion and Petitioner's response as well as the medical records filed in this case, I find that dismissal is appropriate. As discussed in more detail below, because the claim does not meet the Table requirements for a flu vaccine/GBS claim, it is untimely under the Act's "lookback provision" - and even if it had been timely filed, dismissal would still be appropriate because Petitioner cannot satisfy the six-month severity requirement applicable to any Vaccine Act claim.

I. **Procedural History**

After initiation of this case, Petitioner filed documentation showing she received a flu vaccine on September 24, 2012, as alleged. Exhibit 1, filed Mar. 15, 2019, ECF No. 1-2. By April 30, 2018, she had filed the medical records she believed were required to support her claim. Exhibits 2-10, ECF No. 7; Exhibit 11, ECF No. 9; Statement of Completion, ECF No. 10. The initial status conference was scheduled for May 21, 2018.

During the call, the parties discussed whether Petitioner's illness qualified as GBS: whether onset of Petitioner's illness occurred two days after vaccination, and thus too soon for a Table GBS; and whether Petitioner had suffered the residual effects of her illness for more than six months. See Scheduling Order, issued June 7, 2018, ECF No. 11. Petitioner was ordered to file any additional medical records, affidavits, or other evidence to address these issues. *Id.* at 2.

Over the subsequent seven-month period, Petitioner filed additional medical records and affidavits. Exhibits 12-16, filed Sept. 5, 2018, ECF No. 13; Exhibits 17-18, filed Oct. 16, 2018, ECF No. 16; Exhibits 19-20, filed Jan. 15, 2019, ECF No. 20; Statement of Completion, filed Jan. 17, 2019, ECF No. 21. On March 15, 2019, Respondent filed his Rule 4(c) Report, arguing that Petitioner had failed to provide sufficient evidence to address the deficiencies noted during the initial status conference, and a motion, requesting that Petitioner's case be dismissed. ECF Nos. 23-24. In her response, filed on April 12, 2019, Petitioner argued that Respondent's motion was premature and requested that the motion be denied. ECF No. 26.

On August 22, 2019, former Chief Special Master Dorsey³ deferred ruling on Respondent's motion to dismiss. Order, issued Aug. 22, 2019, ECF No. 28. She ordered Petitioner to file an expert report addressing the issues raised by Respondent. *Id.* at 2.

³ This case was initially assigned to former Chief Special Master Dorsey. On October 1, 2019, I was appointed Chief Special Master, and the majority of SPU cases, including this one, were reassigned to me.

During the subsequent eight-month period, Petitioner attempted to procure an expert report to establish that her illness met the definition for Table GBS, and that the effects of her illness had lasted for more than six months. Petitioner first concentrated her efforts on obtaining a report from one of her treating physicians. *E.g.*, First Motion for Extension of Time, filed Oct. 23, 2019, at ¶ 1, ECF No. 29. When unsuccessful, Petitioner attempted to obtain a report from "a specially retained expert." Third Motion for Extension of Time, filed Feb. 21, 2020, at ¶ 1, ECF No. 31. By April 21, 2020, Petitioner indicated her efforts to obtain an expert report had proved unsuccessful. Status Report at ¶ 1, ECF No. 32. Given the constraints imposed by the COVID-19 pandemic, she requested additional time to confer with counsel. *Id.* at ¶ 2. In May and June 2020, Petitioner filed status reports indicating she still was pursing a report from one of her treating physicians, Dr. Ennis. ECF Nos. 33-34.

A call was scheduled for July 28, 2020 to discuss Petitioner's progress. At that time, Petitioner informed me that she would not be filing an expert report or report of a treating physician, but still wished to continue with her claim. Order, issued July 31, 2020, ECF No. 35. In response, it was noted that I had previously determined that the eight-year lookback period does not apply to non-Table flu-GBS claims,⁴ but Petitioner stated that she believed her Table claim did in fact meet the requirements for the claim. Order at 2. The parties were informed that I intended to rule on the issues raised by Respondent in his Rule 4(c) Report and motion to dismiss. Deadlines were set for any additional briefing from the parties.

Petitioner filed her Supplement Brief in Response and Opposition to Respondent's Rule 4(c) Report and Motion to Dismiss ("Opp.") on September 17, 2020. ECF No. 36. Respondent filed his brief, titled as a Motion for Ruling on the Record, on September 23, 2020. ECF No. 38 ("Mot."). Because I already had informed the parties that I intended to rule on the record as it currently stands, the additional deadlines set by Respondent's motion were terminated.

II. Ruling on the Record vs Summary Judgment

A threshold issue raised by the parties' briefs is whether it is appropriate for me to resolve this matter summarily – and if so, what legal standard should apply.

In her brief, Petitioner reiterates the arguments she made in her initial response filed in April 2019. Focusing only on the requirements for summary judgment, Petitioner "contends that her evidence surpasses the low threshold of creating genuine issues of material fact which must be judged on the merits, and requests that the Court set this

⁴ See Randolph v. Sec'y of Health & Human Servs., No. 18-1231V, 2020 WL 542735 (Fed. Cl. Spec. Mstr. Jan. 2, 2020).

matter for further proceedings." Opp. at 4. She maintains that her case "is not appropriate for dismissal because the Respondent failed to establish the absence of genuine issues of material fact." *Id.* In contrast, Respondent argues that a ruling on the existing record is appropriate as "[P]etitioner has admittedly filed all documentation and evidence available in support of her claim." Res. Brief at 4. He maintains that "[i]n its current state, the record is completely insufficient to meet [P]etitioner's burden of proof." *Id.*

In Section 12(d) of the Vaccine Act, Congress provided guidance regarding the type of "less-adversarial, expeditious, and informal" proceeding envisioned for the Vaccine Program. Section 12(d)(2)(A). This guidance was incorporated in the Vaccine Rules. In Vaccine Rule 3, special masters are instructed "to make the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a full and fair opportunity to present its case and creating a record sufficient to allow review of the special master's decision." Vaccine Rule 3(b)(2). And as explicitly set forth in Vaccine Rule 8, "[t]he special master may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions *may* include a motion for summary judgment, in which event the procedures set forth in RCFC 56 will apply." Vaccine Rule 8(d) (emphasis added). Thus, the fact that special masters may make rulings on the record is a product of the Vaccine Act itself, which envisions efforts to streamline proceedings in order to reach faster determinations in a less adversarial manner (especially where the issues that will govern the case's resolution are narrow or primarily legal in nature).

As the Federal Circuit explained when recently affirming my decision to rule on the written record in a different case, a special master's ability to decide a case based upon written submissions without a hearing is *not* limited to the context of summary judgment as applied by the federal courts and civil procedure rules. *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020). Rather, "Rule 8(d) contemplates that special masters can decide cases on written submissions *other* than motions for summary judgment." *Id.* (emphasis in original). As explained in *Kreizenbeck*, special masters may rule on the record after affording the parties "a full and fair opportunity to present its case." *Id.* (citing Vaccine Rule 3(b)(2)). The "special masters must determine that the record is comprehensive and fully developed before ruling on the record." *Kreizenbeck*, 945 F.3d at 1366.

In light of the above, Petitioner is incorrect in maintaining that the summary judgment standards govern the resolution of this matter. Accepting this argument would limit the special masters' authority to decide cases based upon written submissions. But in *Kreizenbeck*, the Federal Circuit clearly stated that the special masters' authority is broader, encompassing the ability to rule on the written without hearing, under standards distinguishable from those applicable to summary judgment. Rather, I may resolve this

case as it stands and on the existing record. The key issue is whether Petitioner has had a full and fair opportunity to offer evidence in support of her claim.

Although a determination was made earlier in the course of the matter to refrain from acting on Respondent's motion – in order to allow Petitioner the chance to develop the record - those circumstances have changed. As presented in April 2019, Petitioner's arguments were enough to warrant deferring a ruling on Respondent's motion to dismiss, since she had not yet had the opportunity to fully address the issues raised by Respondent. However, since that time, Petitioner has been afforded *more than a year* to obtain an expert report but has failed to do so. She also could have filed additional information or evidence bearing on the claim.

Under the Act, a petitioner must demonstrate by preponderant evidence the requirements for a petition as set forth in section 11(c)(1). Section 13(a)(1)(A). It cannot be said that resolution of this matter now, on the basis of the existing record, is depriving Petitioner of the opportunity to prove a matter, since she has been given ample time to do so. I therefore find that resolution of the pending motion, based on the authority vested in me as recognized by the Federal Circuit, is appropriate at this time – and I need not be guided by summary judgment fact-finding standards in so doing.

III. Analysis of Substantive Issues Raised by Respondent's Motion

A. Adequacy of Table Claim

Pursuant to the Vaccine Injury Table, GBS is compensable if it manifests within 3-42 days after the administration of a flu vaccine. 42 C.F.R. § 100.3(a)(XIV)(D) (2017). Additional criteria can be found in the *Qualification and Aids to Interpretation ("QAI")*. 42 C.F.R. § 100.3(c)(15). Respondent argues that Petitioner's case fails on several areas.

First, Respondent maintains that the onset of Petitioner's symptoms does not fit the Table period. Petitioner received the flu vaccine on September 24, 2012, while hospitalized for esophageal surgery performed five days earlier (September 19, 2012). Exhibit 5 at 39-40. The exact time of administration is not clearly noted in the vaccine record, but it appears it may have been administered at approximately 10:01 am. Exhibit 1 at 9. Under the Table's timeframe, onset would have to be no earlier than the morning of September 27th.

On Saturday, September 29, 2012, Petitioner visited the emergency room, complaining of lower extremity weakness and numbness. Exhibit 5 at 10. She initially reported to treaters at this time that she had been experiencing these symptoms for three days. Normally, this would place onset as occurring on September 26, 2012, or two days

after vaccination (and hence too short to meet the Table timeframe). However, Petitioner also identifies onset as occurring on Thursday morning when she woke. *Id.* This would place onset early on September 27, 2012 - close to but not quite three days after vaccination. Later histories are less exact, but all place onset around approximately the same time.

Given the above, the question of onset in this case remains a close call. Under such circumstances, relevant and persuasive case law suggests deciding the issue in Petitioner's favor. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005). Were this the sole issue with the adequacy of the Table claim, I would likely find this matter in Petitioner's favor.

There is, however, a second and far more problematic issue: whether the illness Petitioner suffered was GBS or some other condition. There is no clear GBS diagnosis in the medical records filed by Petitioner, and her symptoms are often reported to be atypical.⁵ In fact, on several instances, Petitioner's treating physicians theorized that her symptoms may be psychosomatic.⁶

When Petitioner first sought treatment on September 29, 2012, she visited her primary care provider William L. Pridgen, M.D., before going to the hospital. Exhibit 4 at 23-24. She had seen Dr. Pridgen six days earlier on September 23, 2012, complaining of nausea, vomiting, and the feeling of a tear when throwing up. *Id.* at 25. At that visit, Dr. Pridgen indicated Petitioner was not taking her medicine and thus had likely experienced a viral activation that needed to be suppressed with medication. *Id.*

When she returned to Dr. Pridgen's office, complaining of weakness and numbness in her lower extremities, Dr. Pridgen attributed her symptoms to the same viral flare he had opined that she was experiencing, noting that according to Petitioner and her family she had experienced "transient lower extremity paralysis . . . in the past . . . [when] on suppression therapy, . . . certainly during non-treatment, which is the reason for the suppression in the first place." Exhibit 4 at 23. According to Dr. Pridgen, "that is exactly

⁵ For example, in the medical records from an emergency room consult on October 26, 2012, it is noted that "[r]eview of her clinical course is somewhat atypical in that spinal fluid analysis was negative and the patient had sensory involvement." Exhibit 10 at 129.

⁶ In an October 3, 2012 note in the medical records from DCH Hospital, it is noted that some lower performance "may be supratentorial." Exhibit 5 at 31. Supratentorial means superior to the tentorium of the cerebellum. Dorland's Illustrated Medical Dictionary ("Dorland's") at 1806. Thus, this entry appears to be a complex way of saying in her head. A much clearer statement can be found in a DCH Hospital medical records from October 31, 2012. The statement is as follows: "Neurology saw the patient. There was some concern that some of the symptoms could be psychosomatic related." Exhibit 10 at 117. Psychosomatic means "pertaining to the mind-body relationship; having bodily symptoms of psychic, emotional, or mental origin." Dorland's at 1550.

what happened here." *Id.* Petitioner had previously been diagnosed with Henoch-Schonlein Purpura⁷ when 10 years old.

Later entries show other treating physicians similarly uncertain of a GBS diagnosis. For example, in the medical records from an October 8, 2012 consultation, the treating physician questioned whether the proper diagnosis was an inflammatory response such as GBS vs. toxic neuropathy. Exhibit 5 at 36. Regarding a second bout of lower extremity numbness suffered by Petitioner on October 26, 2012, there is a reference to a UTI (urinary tract infection) and Petitioner acknowledges that she again was taking HSV medication intermittently. Exhibit 10 at 118, 124.

The discussion in this section provides a few examples of the information contained in the medical records casting significant doubt on whether Petitioner's illness satisfies the Table definition of GBS, or can even be properly characterized as GBS. But a petitioner cannot prevail on a Table claim if she cannot satisfy the Table's definition for the injury. Here, the existing record preponderates against the conclusion that Petitioner did in fact experience GBS. Moreover, Petitioner has been given ample opportunity to supplement that record – here, with an expert report that could synthesize the record and explain how GBS is the proper diagnosis despite a lack of treater record support. Examining the whole record in this case, I find that Petitioner has not provided preponderant evidence showing her illness meets the Table definition for GBS.

B. Untimeliness of Claim

In many cases, the fact that a claimant cannot meet a Table definition or requirement does not constitute the end of the case, since the claimant might well be able to establish a non-Table, causation-in-fact version of the claim not subject to those requirements. Here, for example, Petitioner might be able to show that her injury (whatever it is) is some kind of GBS-like neuropathy caused by the flu vaccine. (She would, of course, then be obligated to meet the three elements of the test set forth in *Althen*, 418 F.3d at1278).

But Petitioner's ability to refashion her claim into a non-Table cause of action is not possible under the circumstances, due to the late date the matter was filed. It is not disputed that Petitioner received the flu vaccine on September 24, 2012. Accordingly, to be timely filed under the Vaccine Act's 36-month statute of limitations, Petitioner should have filed her petition by no later than a date in September 2015 (based upon onset).

⁷ Henoch-Schonlein Purpura is a disorder causing inflammation and bleeding in the small blood vessels. See https://www.webmd.com/skin-problems-and-treatments/henoch-schonlein-purpura-causes-symptoms-treatment#1 (last visited on Oct. 27, 2020).

Section 16(a)(2). But this matter was initiated in *March 2018* – approximately two and one-half years later. It is thus facially untimely.

Petitioner argues the contrary, relying on the Act's "lookback" provision (Section 16(b)). Opp. at 1. That provision is triggered by a Table revision, and allows petitioners to file otherwise-untimely petitions within two years of the revision's effective date, for vaccine-related injuries suffered during the eight years prior to the revision. Section 16(b). Thus, Petitioner maintains, because the Vaccine Table was revised in 2017⁸ to include a claim for GBS after receipt of the flu vaccine, the present claim (filed a year after the Table change) is timely since it alleges a Table claim.

Petitioner's reasoning is incorrect. I have previously determined that the "lookback" provision of the Vaccine Act "does not save a *non-Table* version of a flu-GBS claim." *Randolph v. Sec'y of Health & Human Servs.*, No. 18-1231V, 2020 WL 542735, at *8 (Fed. Cl. Spec. Mstr. Jan. 2, 2020) (emphasis added). Rather, once it is determined that any particular claim cannot satisfy the Table requirements, the lookback provision no longer applies. My determination is in line with prior decisions from other special masters. *Gorski v. Sec'y of Health & Human Servs.*, No. 97-156V, 1997 WL 739497, at *6 (Fed. Cl. Spec. Mstr. Nov. 13, 1997).

Here, my conclusion that Petitioner cannot preponderantly meet the requirement of a flu-GBS Table claim takes her out of the lookback's safe harbor. Because Petitioner filed her case well after the expiration of the Vaccine Act's 36-month statute of limitation, her petition is untimely filed, and thus must be dismissed.

C. Severity Requirement

In addition to the foregoing, dismissal is also warranted because Petitioner cannot demonstrate that she suffered the residual effects of her illness for more than six months.

The last mention of lower extremity weakness and numbness can be found in the medical records from treatment Petitioner received in late October 2012 for her second bout of these symptoms. This was less than two months from onset. Thereafter, Petitioner suffered from right hand parenthesis and weakness on May 23, 2013. Exhibit 10 at 58. However, the medical record from that visit establishes that the treating physician clearly opined that "[t]he patient's examination is not consistent with Guillan barre [sic]." *Id.* at 63. Petitioner visited the emergency room again on July 3, 2013, complaining of a migraine.

⁸ Effective for petitions filed beginning on March 21, 2017, GBS is an injury listed on the Table. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule, 82 Fed. Reg. 6294 (Jan. 19, 2017); National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date, 82 Fed. Reg. 11321 (Feb. 22, 2017) (delaying the effective date of the final rule until March 21, 2017).

Id. at 20. Again, there is nothing in this medical record to link these symptoms to the illness Petitioner suffered in October 2012. *Id.* at 20-44. Thus, the last symptom that arguably could be linked to GBS occurred in late October/early November 2012, less than two months after vaccination.

This record is insufficient to satisfy the Vaccine Act's six-month statutory requirement for severity. Section 16(c)(1)(D)(i). Not only can she not demonstrate that she ever received a formal GBS diagnosis, but she cannot show that the symptoms that arguably reflected GBS close-in-time to vaccination persisted or produced other sequelae that lasted over time. Here, expert interpretation of the record would have potentially been helpful – but despite the opportunity to provide it, Petitioner failed to file any such report. This thus stands as another, independent basis for the claim's dismissal.

IV. Conclusion

To date, and despite ample opportunity, Petitioner has failed to file preponderant evidence to establish her Table claim, rendering the case untimely. She also cannot meet the severity requirement applicable to all Program claims. Accordingly, this case is DISMISSED for failure to prosecute. The clerk shall enter judgment accordingly.⁹

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master

⁹ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.